COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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Through: Scott Bookman, Director, DCPHR *SB*

Date: March 15, 2023

Subject: Rulemaking Hearing concerning 6 CCR 1009-2, The Infant Immunization Program and Immunization of Students Attending School

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Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Engagement, and Proposed Amendments to 6 CCR 1009-2, The Infant Immunization Program and Immunization of Students Attending School.

The Colorado Department of Public Health and Environment (Department) has the legal authority, established in Colorado law, to protect students and the general population from vaccine-preventable diseases. Childcare facilities, schools, and colleges/universities are bound by law to ensure students meet the vaccine requirements established by the Colorado Board of Health (Board). Colorado's vaccine requirements have contributed to higher vaccine coverage, lower levels of vaccine-preventable disease, and fewer disruptions to in-person learning.

The proposed amendments in this request to rulemaking include minor changes to rule language in several sections. These proposed changes are primarily technical in nature and are intended to clarify existing rule language and/or provide better alignment with current medical practice.

These changes include:

- Amending definitions in Section I (G, I, and Q), Section V (A), and Section IX (B)(2)(a) to incorporate the use of gender-neutral pronouns.
- Amending definitions in Section I (O and R) to address online-only educational programs where the enrolled student is physically present at the educational institution for participation in enrichment, athletics, or other activities.
- Amending definitions in Section I (O.1) to exclude homeless youth shelters, as defined in Section 26-6-903(13), C.R.S., from the definition of schools.

- Revising language in Section II (E) and Section IX (A) to clarify the acceptable use of titers as alternatives to vaccines required for school entry. A titer, or laboratory test to measure the presence and amount of antibodies in blood, may be used to prove immunity to certain diseases. If the test is positive (above a value known to show immunity) the individual has immunity. If the test is negative (no immunity) or equivocal (not enough immunity), the individual may need to be vaccinated.

Since the request for rulemaking hearing in January 2023, the Department has been considering the continued relevance of positive hepatitis B titers within the context of school vaccine requirements. Per guidance developed by the Advisory Committee on Immunization Practices (ACIP), a positive titer for hepatitis B may provide evidence of protection only after the completion of an approved hepatitis B vaccine series. In the school setting, when a student provides documentation of completion of an appropriate hepatitis B vaccine series in alignment with ACIP guidelines, they would already be in compliance with current hepatitis B school entry requirements, making a positive titer for hepatitis B unnecessary. Based on this analysis, the Department is now proposing one substantive change to this rule:

- Revising language in Section II (E) (4) to clarify that a titer is not an acceptable alternative for hepatitis B vaccination.

In total, the proposed amendments are necessary to continue to bring clarity to the rules, adhere to evolving medical standards and minimize potential confusion among end-users of the rule.

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. A summary of the feedback received and, if the Department incorporated this feedback, is detailed in the Stakeholder Engagement section.

Changes to rule language appear in ALL CAPS and strikethroughs. Any new or modified language is highlighted in yellow.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-2 The Infant Immunization Program and Immunization of Students Attending School

Basis and Purpose.

Colorado requires all students to be immunized per the vaccine schedule established by Colorado Board of Health (BOH) rule 6 CCR 1009-2 upon school entry unless a Certificate of Medical or Nonmedical Exemption is filed. The purpose of the immunization requirements for school entry is to protect students, staff, and the visiting public against vaccine-preventable diseases within schools.

The Colorado Department of Public Health and Environment (Department) proposes several changes to the rule that are intended to:

- Adhere to evolving medical standards;
- Continue to bring clarity to the rule;
- Minimize potential confusion among end-users of the rule; and
- Simplify the language of the existing rule.

The proposed changes were the result of an internal review of the existing rule, feedback received from stakeholders, and consideration of best practices.

To this end, the following changes to the rule are proposed:

First, the Department proposes amending the definitions in Section I (G, I, and Q), Section V (A), and Section IX (B)(2)(a) to incorporate the use of gender-neutral pronouns. Adopting this gender-neutral language is one way this rule can be inclusive of a range of people and identities, minimize harm for people who are non-binary, and foster inclusion and respect.

Second, the Department proposes modifications to definitions in Section I (O and R) to address online-only educational programs where the enrolled student is physically present at the educational institution for participation in enrichment, athletics, or other activities. The intent of the proposed modification is to clarify that immunization records are required for students who attend an online-only school if or when they have some physical presence and interaction with others at the school. The Department has seen an increase in the number of students who participate in online-only educational programs since the onset of the COVID-19 pandemic. The proposed modifications remain consistent with the definitions of "Online School" authorized pursuant to Title 22 of the Colorado Revised Statutes.

Online-only educational programs are separate and distinct from homeschooling. Home-based educational programs are considered nonpublic and are not regulated by the state of Colorado. The parent who oversees the home school program is taking on the responsibility of obtaining books, supplies, tests, and is responsible for any costs associated. Because home schooling is considered nonpublic education, home school is not accredited by the Colorado

Department of Education or by a local school district. In contrast, online-only educational programs may be affiliated with or part of the public school system. One example is the Jeffco Virtual Academy which is part of Jefferson County Public Schools.

Third, the Department proposes amending definitions in Section I (O.1) to exclude homeless youth shelters, as defined in Section 26-6-903(13), C.R.S., from the definition of schools. In the past several weeks, the Department has been made aware that homeless youth shelters consistently face significant challenges in collecting immunization records for the children and youth they serve. To address these challenges and to ensure youth experiencing homelessness are not excluded from shelters, the Department is now proposing to exclude homeless youth shelters as defined in Section 26-6-903 (13), C.R.S. from the definition of a school in Section I (O.1) of this rule. Homeless youth shelters serve youth who are at least 11 years of age or older. Minors accessing these shelters remain enrolled in their schools and either attend school and/or gather classroom assignments from their school during their stay at the shelter (up to 21 days). While homeless youth shelter staff make good faith efforts to obtain immunization records from the youth they serve, the schools where these minors are enrolled would have their immunization records or certificates of exemption on file.

Fourth, the Department proposes revising language in Section II (E) and Section IX (A) to clarify the acceptable use of titers as alternatives to vaccines required for school entry. A titer, or laboratory test to measure the presence and amount of antibodies in the blood, may be used to prove immunity to certain diseases. If the test is positive (above a value known to show immunity) the individual has immunity. If the test is negative (no immunity) or equivocal (not enough immunity), the individual may need to be vaccinated.

Here, the proposed language clarifies that:

- Positive titers are acceptable alternatives to tetanus and diphtheria components of the pertussis-containing DTaP and Tdap vaccines required for school entry, but titers are not acceptable alternatives to the pertussis component of either vaccine. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) guidance states, "There is no serology test that can adequately document immunity to pertussis, so the utility of a test or titer to measure immunity for 'DTaP' is minimal." The Department will only accept documentation of positive titers for tetanus and diphtheria and thus require either:
  1. Vaccination with an age-appropriate pertussis-containing vaccine series in alignment with ACIP, or
  2. A Certificate of Medical or Nonmedical Exemption for the pertussis component of the DTaP/Tdap vaccine.

- The acceptable use of positive titers for measles, mumps, and rubella (MMR) requires that all three titers be positive. The Department will only accept documentation of positive titers for MMR if all three titers are positive. If any single titer is negative, the Department will require:
  1. Vaccination with an age-appropriate MMR vaccine series in alignment with ACIP, or
  2. A Certificate of Medical or Nonmedical Exemption for the component(s) for which the titer is negative

Finally, since the request for rulemaking hearing in January 2023, the Department has been considering the continued relevance of positive hepatitis B titers within the context of school

vaccine requirements. Per guidance developed by the Advisory Committee on Immunization Practices (ACIP), a positive titer for hepatitis B may provide evidence of protection only after the completion of an approved hepatitis B vaccine series.[1,2] In the school setting, when a student provides documentation of completion of an appropriate hepatitis B vaccine series in alignment with ACIP guidelines, they would already be in compliance with current hepatitis B school entry requirements, making a positive titer for hepatitis B unnecessary. Based on this analysis, the Department is now proposing one substantive change to this rule:

- Revising language in Section II (E) (4) to clarify that a titer is not an acceptable alternative for hepatitis B vaccination.

Hepatitis B is a vaccine-preventable disease caused by an infection with the hepatitis B virus (HBV) that causes damage to the cells of the liver. This damage may have no symptoms, or could lead to pain, jaundice (yellowing of the skin or eyes), fever, nausea, vomiting, fatigue, or confusion. Chronic (long-term) hepatitis B can cause liver damage, liver failure, liver cancer, and death.

HBV is highly infectious and can remain viable and transmissible on environmental surfaces for at least seven days, even in the absence of visible blood. HBV spreads through contact with an infected person's blood, semen or vaginal fluid, or other body fluids. The virus can be transmitted from a birthing parent to their baby during birth, between sexual partners, between people who share needles or other devices that come in contact with blood or body fluid, or through direct exposure to the blood or body fluid of an infected person, for example, in health care settings.

Today, between 880,000 to 1,890,000 people are living with hepatitis B virus (HBV) in the United States, with two out of three people unaware of their infection. There is no cure, but there is a safe and effective vaccine to prevent hepatitis B infection and its potentially serious complications.

The first hepatitis B vaccine was licensed in the United States in 1986. In 1991, the United States adopted a strategy for universal hepatitis B vaccination of infants, followed by a national standard of care intended to eliminate HBV transmission in people of all ages.

This includes:

1. Routine screening to identify hepatitis B virus in all pregnancies.
    a. When infants are born to people who have lab tests that are positive (or unknown) for hepatitis B, administration of hepatitis B immune globulin (HBIG) and the hepatitis B vaccine immediately after birth can prevent 94% of transmission of HBV from parent to infant. Thus, all people who are pregnant are recommended to be screened for hepatitis B during every pregnancy.
2. Hepatitis B vaccination of all infants beginning at birth.
    a. The focus of the hepatitis B birth dose and on-time completion of the hepatitis B vaccination series during the first year of life is crucial as risk of chronic infection is related to age at infection:
        i. Chronic infection develops in approximately 90% of infants after acute infection at birth, 25–50% of children newly infected at ages 1–5 years, and 5% of people newly infected as adults.
3. Routine hepatitis B vaccination for unvaccinated and undervaccinated children and adolescents.

4. Routine hepatitis B vaccination for all unvaccinated and undervaccinated adults aged 19 through 59 years; adults aged 60 years or older with risk factors for hepatitis B infection; and adults who are 60 years or older without known risk factors for hepatitis B but who are interested in receiving hepatitis B vaccine.

Hepatitis B vaccination coverage in Colorado varies by age range. In Colorado, the birth dose completion rate for the hepatitis B vaccine was 84.3% in 2020 and 83.4% in 2021. According to aggregate, de-identified data collected by CDPHE annually from Colorado schools, 95.0% of 2020-21 school-aged (Kindergarten through 12th grade) students had completed the hepatitis B series. The following school year, 94.8% of 2021-22 school-aged students had completed the hepatitis B series.

Hepatitis B vaccine has been required for school entry in Colorado for 25 years. The Department is NOT proposing a change to the requirement itself, but rather proposing a change regarding the use of a titer as an alternative means to meet the existing school entry immunization requirement. As stated above, guidance developed by the ACIP asserts that a positive titer for hepatitis B may provide evidence of protection only after the completion of an approved hepatitis B vaccine series. In the school setting, when a student provides documentation of completion of an appropriate hepatitis B vaccine series in alignment with ACIP guidelines, they would already be in compliance with current hepatitis B school entry requirements, making a positive titer for hepatitis B unnecessary.

Outside of the school setting, there are some populations where a hepatitis B titer can be useful to test for and document immunity, including health care personnel (HCP) and infants born to individuals infected with hepatitis B virus (HBV)[1].

- The CDC recommends all HCP, including trainees, who have a high risk of work exposure to blood or body fluids (for example, HCP with direct patient contact, HCP at risk of needlestick or sharps injury, laboratory workers who draw, test, or handle blood specimens) should receive a hepatitis B titer test following the completion of an approved hepatitis B vaccination series to assess for adequate immune response.
- Similarly, infants born to people living with HBV should receive a hepatitis B titer test following the completion of an approved hepatitis B vaccination series. HBV infection in a person who is pregnant poses a serious risk to the infant at birth. Most infants, approximately 90%, who are infected with HBV will develop chronic infection and 25% will die prematurely from liver cancer or cirrhosis (scarring of the liver).

Due to their increased risk, hepatitis B titers help with understanding when and how much these infants and HCPs are protected from this harmful virus. For the majority of the population, hepatitis B titers are not necessary. The hepatitis B titer does not have broad applicability within the school setting.

Research shows that more than 90% of infants, children, adolescents, and healthy adults under the age of 40 develop protective immune responses following a complete hepatitis B vaccination series, and the hepatitis B vaccine is 80-100% effective in preventing infection or clinical hepatitis when a person receives an approved vaccine series. Vaccination for hepatitis B remains the best and safest way to prevent hepatitis B infection and is recommended by the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American College of Nurse-Midwives, the American Academy of Physician Associates, the National Association of Pediatric Nurse

Practitioners, the American Pharmacists Association, and the Society for Healthcare Epidemiology of America.

In total, the proposed changes are intended to clarify existing rule language and provide better alignment with current medical practice.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

§ 25-4-904, C.R.S.

Is this rulemaking due to a change in state statute?
_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
___x___ No
Does this rulemaking include proposed rule language that incorporate materials by reference?
_____ Yes ___ URL
___x___ No

Does this rulemaking include proposed rule language to create or modify fines or fees?
_____ Yes
___x___ No

Does the proposed rule language create (or increase) a state mandate on local government?
_x__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for amendments to
6 CCR 1009-2 The Infant Immunization Program and Immunization of Students Attending School

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Approximately 2,150 public and private schools, approximately 2,100 licensed child cares, thousands of healthcare providers throughout the state, the Colorado Department of Education, the Colorado Department of Human Services, the Colorado Department of Higher Education, the Colorado Office of Early Childhood, approximately 25 colleges/universities and 56 county, district or municipal public health agencies (LPHAs) rely on the rule to maintain their own businesses, agencies or operations.		C, CLG
Students enrolled in Colorado schools and, if under 18 years of age, their parents/legal guardians, and the public at large.		S, B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.
CLG = local governments that must implement the rule in order to remain in compliance with the law.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

The Department does not foresee an economic impact to any affected persons. The proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule and better alignment with current medical practice; both of which the Department expects will result in improved customer experience.

Non-economic outcomes
Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

Favorable non-economic outcomes:

C, CLG, B, S: The proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule and better alignment with current medical practice; all of which the Department expects will result in improved customer experience. The addition of gender-neutral pronouns will result in greater inclusivity. In addition, in circumstances where an individual is unable to obtain copies of their complete vaccination history, or who believes they have already contracted and recovered from the disease in question, the proposed clarifications regarding the use of which positive titers (above a value known to show immunity) are an acceptable alternative to proof of vaccination could allow that individual to avoid unnecessary additional vaccination.

Unfavorable non-economic outcomes: N/A

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

The proposed amendments are cost-neutral.

Anticipated CDPHE Revenues: N/A

B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

___ Comply with a statutory mandate to promulgate rules.
___ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X__ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
_x__ Improve public and environmental health practice.

_x__ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. _X__ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30,

2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.
___ Optimizes processes prior to digitizing them.
___ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.

___ Reduces emissions from employee commuting
___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.

___ Used a budget equity assessment

X___ Advance CDPHE Division-level strategic priorities.

- Identify division strategic plan item or strategic priority

Reverse the downward trend in vaccination rates by achieving a goal of 91% vaccination rate for MMR and DTaP in kindergarten-aged children by June 30, 2023, towards a long-term goal of reaching 95%.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include: NA

Inaction has neither monetary cost nor benefit; however, inaction results in misalignment with best practices in the medical field and potential confusion regarding rule language and requirements as well as continued non-inclusive use of gender-specific pronouns.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. For this rule, both apply. As there is no anticipated cost of compliance with the proposed amendments to the rule, there is no less costly method to achieve the purpose of the rule. Additionally, the Board of Health is required by section 25-4-904, C.R.S. to "establish rules and regulations for administering this part 9." Furthermore, the proposed amendments should strengthen the Department's partnership with community partners in schools, childcares and colleges and universities as the proposed amendments clarify or simplify existing requirements.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

The alternative to rulemaking is to maintain the rules in their current form. This option was rejected to ensure that the rules are consistent with advances in the medical field and in alignment with current best practices.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The Department conducted an extensive review of the Advisory Committee on Immunization Practices (ACIP) guidance for serology as proof of vaccination and/or protection against certain diseases.

Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP): https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices: https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

Vaccine Recommendations and Guidelines of the ACIP: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html

Measles, Mumps, Rubella Vaccine (PRIORIX): Recommendations of the Advisory Committee on Immunization Practices — United States, 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7146a1.htm

Use of Serology to Aid in the Diagnosis of Mumps Infection: https://www.cdc.gov/mumps/lab/overview-serology.html#neutralizing

Vaccine Recommendations and Guidelines of the ACIP: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html#:~:text=%E2%80%94-,MMR,-Revaccination%20with%20MMR

Prevention of Varicella: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm

Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1009-2 The Infant Immunization Program and Immunization of Students Attending School

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The Department developed the proposed rules and has sought feedback through an early stakeholder engagement process. These early efforts included sending an email notification of upcoming rule changes, summarization of draft proposed changes, a strike-through version of the draft proposed rule text, and a dedicated online survey where staff could collect feedback from stakeholders.

Feedback was solicited from approximately 28,000 individuals representing: members of the public, parents/students, LPHAs, Federally Qualified Health Centers, Community Health Clinics, Rural Health Centers, Hospitals, Colorado colleges and universities, Vaccines for Children providers, Colorado Immunization Information System (CIIS) users, Colorado Association of Physician Assistants, local immunization coalitions, school nurses, child care health consultants, Colorado schools and child care facilities, Colorado Children's Campaign, Colorado Academy of Family Physicians, the Colorado Medical Society, Colorado Chapter of the American Academy of Pediatrics, Immunize Colorado, Colorado Coalition for Vaccine Choice, Colorado Student Health Services Consortium, National Vaccine Information Center, Colorado Immunization Advocates, Colorado Health Choice Alliance, the Weston A. Price Foundation, Voices for Vaccines, the Colorado Department of Education, Christian Home Educators of Colorado, the Colorado Department of Human Services, and the Colorado Office of Early Childhood.

Stakeholder Group Notification
The Department provided notice to interested parties of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

_____ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking. This is selected for the request for rulemaking.

__X__ Yes. This is selected for the rulemaking to document that timely division notification occurred.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. The Department sent an email notification to interested parties about the rulemaking and proposed changes on Dec. 1, 2022, Feb. 10, 2023, and Feb. 20, 2023. Each email notification contained a strikethrough version of the proposed changes and a link to an online form where interested individuals could submit informal feedback or questions directly to the Immunization Branch.

To date, the Department has received informal feedback from 157 email communications out of approximately 28,000 stakeholders contacted. The Department also received 75 responses via the online form.

The Department received a few questions through the engagement process. To the extent possible, the Department responded to stakeholders who asked clarifying questions or referred them to publicly available information on our website.

Below is a summary of feedback received from stakeholders and how the Department is responding to the suggestions, including feedback regarding proposed rule language:

- The Department received an email stating that if the decision was made to keep antibody titer testing in place, then having more restrictive provisions for use and interpretation seems appropriate. The communication also requested the Department consider adding provisions regarding the type of antibody testing (e.g., IgG from commercial laboratory with a validated assay) should there be questions raised about the accuracy of the result. The Department conducted an extensive review of the suggestions in the communication and made very minor modifications to the proposed language. The Department acknowledges that the use of titer testing and interpretation of results is an area of some complexity. The Department will develop and share a resource document that healthcare providers, childcare providers and school nurses could use to provide consistency in determinations about titer testing and results. We believe this resource document coupled with technical assistance provided by Department staff will lessen the burden on providers and school staff as they make appropriate determinations regarding titer testing.

- The Department received feedback in opposition to the recommended changes proposing gender-neutral pronouns. The Department will proceed with the proposed changes as adopting gender-neutral language is one way this rule can be inclusive of a range of people and identities.

- The Department received feedback conveying general support of the proposed changes.

- The Department received significant feedback in opposition to any immunization mandates. These comments are outside the scope of this rulemaking as the Department is not proposing any new immunization requirements.

- The Department received email communications stating concerns about the proposed language in Section I (R). These concerns centered around two issues - 1) the definition of a student as it pertains to whom immunization records may be collected from, and 2) how the provisions of Senate Bill 2020-163 might contradict the proposed new language in this Section.

  The Department believes that the individuals providing this feedback could have misread the proposed new definition of student in Section I (R). The Department is proposing the language in ALL CAPS below:

  > R. Student - any person enrolled in a Colorado school as defined in section I (O), **except:**
  >
  > A CHILD WHO ATTENDS EDUCATIONAL PROGRAMS WHERE COURSES ARE OFFERED ONLINE ONLY AND THE CHILD IS NOT PHYSICALLY PRESENT AT THE INSTITUTION FOR PARTICIPATION IN ENRICHMENT, ATHLETICS, OR OTHER ACTIVITIES.

  First, proposed changes to the definition of a student specifically EXCLUDE a student who attends an educational program where courses are offered online only and that student does NOT have any physical presence at the institution for enrichment, athletics, or other activities. With this exclusion, the Department establishes that it is not seeking immunization records for these individuals who do not have any physical presence at the institution for enrichment, athletics, or other activities.

  Second, the Department received email communications stating that the inclusion of homeschooled students in vaccine requirements is in direct conflict with the provisions of Senate Bill 2020-163. These provisions of Senate Bill 2020-163 reference students participating in a nonpublic home-based educational program (Section 22-33-104.5, C.R.S.).

  Here, where the rule text refers to courses that are offered online only, the rule is intending to reference online programs as defined in 1 CCR 301-71 and authorized pursuant to Section 22-30.7-105, C.R.S. These terms are defined as follows:

  > "Online Program" means a full-time education program authorized pursuant to Title 22 of the Colorado Revised Statutes that delivers a sequential program of synchronous or asynchronous instruction directed by a teacher primarily through online digital learning strategies that provide students choice over time, place, and path, and teacher-guided modality of learning. "Online Program" does not include a supplemental program. Accountability for each student in an online program is attributed back to a designated school that houses the online program. An Online Program with one hundred or more students is an Online School and not an Online Program
  >
  > "Online School" means a full-time, education school authorized pursuant to Title 22 of the Colorado Revised Statutes that delivers a sequential program of

synchronous or asynchronous instruction directed by a teacher primarily through online digital learning strategies that provide students choice over time, place, and path, and teacher- guided modality of learning. An Online School has an assigned school code and operates with its own administrator, a separate budget, and a complete instructional program. An Online School is responsible for fulfilling all reporting requirements and is held to state and federally mandated accountability processes.

The Department believes that Senate Bill 2020-163 does not contemplate students attending online schools or online programs and thus only extends exceptions to those students who attend a home-based education program as defined in Section 22-33-104.5, C.R.S.

The Department acknowledges that the distinction between these different types of educational programs could be made more clear in rule text and has proposed revised rule language to make this distinction clearer.

- The Department also received multiple email communications stating that Section IX of the rule should clarify the exclusion of vaccine requirements for older adults in college. The communications state that it is unduly burdensome for colleges and universities to require older, non-traditional adult students to provide their childhood vaccine records they may no longer have in their possession. The Department believes that the proposed language in Section IX, will allow the Department a new opportunity to educate colleges about the appropriate uses of titer testing - especially among older students who may no longer have access to their childhood vaccine records.

  Here again, the proposed language clarifies that the acceptable use of positive titers for measles, mumps, and rubella (MMR) requires that all three titers be positive. The Department will only accept documentation of positive titers for MMR, if all three titers are positive. If any single titer is negative, the Department will require:
  1. Vaccination with an age-appropriate MMR vaccine series in alignment with ACIP, or
  2. A certificate of medical or nonmedical exemption for the component(s) for which the titer is negative.

  The Department appreciates this feedback and will highlight this new language in its outreach to colleges and other institutes of higher education.

- The Department received feedback regarding the initial proposed new language titers for measles, mumps, or rubella (MMR). This commenter interpreted the new language to mean that a person only needs one dose of MMR vaccine if any component is negative on a titer test. The Department understands how the initial proposed language may be interpreted that way and is now proposing slight revisions around all titer language for enhanced clarity. The Department appreciates this feedback and the opportunity to further refine rule language.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking. Consider if the rulemaking will

improve the experience or outcomes for previously disenfranchised, un-served or underserved, or marginalized populations or the network of partners (state agencies, local governments, community-based organizations, etc.) that serve disenfranchised, un-served or underserved populations. Please review #1.C above and the Social Determinants of Health Planning Tool to help complete this portion of the packet.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
x	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.	x	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
x	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.	x	Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Public Health Response Division

THE INFANT IMMUNIZATION PROGRAM AND IMMUNIZATION OF STUDENTS ATTENDING SCHOOL

6 CCR 1009-2

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

I. Definitions

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G. Emancipated student - any student who has reached 18 years of age; a lawfully married child of any age; a child 15 years of age or older who is managing ~~his/her~~ THEIR own financial affairs and who is living separate and apart from ~~his/her~~ THEIR parent.

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I. Indigent child - any child whose parent cannot afford to have the child immunized or if emancipated, who cannot ~~himself/herself~~ THEMSELF afford immunization and who has not been exempted.

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O. School - all child care facilities licensed by the Colorado Department of Human Services including: Child care centers, school-age child care centers, preschools, day camps, resident camps, day treatment centers, family child care homes, foster care homes, and head start programs; public, private, or parochial kindergarten, elementary, or secondary schools through grade twelve, or a college or university. SCHOOLS INCLUDE EDUCATIONAL PROGRAMS WHERE COURSES ARE OFFERED ONLINE (AN ONLINE SCHOOL OR PROGRAM AS DEFINED IN 1 CCR 301-71) BUT WHERE ENROLLED STUDENTS ARE PHYSICALLY PRESENT AT THE INSTITUTION FOR PARTICIPATION IN ENRICHMENT, ATHLETICS, OR OTHER ACTIVITIES.

1. Schools do not include a public services short-term child care facility as defined in section ~~26-6-102~~ 26.5-5-303(30), C.R.S., a guest child care facility as defined in section ~~26-6-102~~ 26.5-5-303(16), C.R.S., a ski school as defined in section ~~26-6-103.5~~ 26.5-5-307 (6), C.R.S., A HOMELESS YOUTH SHELTER AS DEFINED IN SECTION 26-6-903(13), C.R.S., or college or university classes which are: Offered off-campus; offered to nontraditional adult students as defined by the governing board of the institution; offered at colleges or universities which do not have residence hall facilities, or; a school whose normal course of student Instruction is delivered online only.

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Q. School official - the school's chief executive officer or any person designated by ~~him/her~~ THEM as ~~his/her~~ THEIR representative.

R. Student - any person enrolled in a Colorado school as defined in section I (O), except:

1. A CHILD WHO ATTENDS EDUCATIONAL PROGRAMS WHERE COURSES ARE OFFERED ONLINE (AN ONLINE SCHOOL OR PROGRAM AS DEFINED IN 1 CCR 301-71) AND THE CHILD IS NOT PHYSICALLY PRESENT AT THE INSTITUTION FOR PARTICIPATION IN ENRICHMENT, ATHLETICS, OR OTHER ACTIVITIES.

~~1.~~ 2. A child who enrolls and attends a licensed child care center, as defined in section ~~26-6-102~~ 26.5-5-303(5), C.R.S., which is located at a ski area, for up to fifteen days or less in a fifteen-consecutive-day period, no more than twice in a calendar year, with each fifteen-consecutive-day period separated by at least sixty days, and

~~2~~. 3. College and university students as defined in section I (C).

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II. Minimum Immunization Requirements

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E. LABORATORY CONFIRMATION OF POSITIVE TITERS IS AN ACCEPTABLE ALTERNATIVE TO THE FOLLOWING VACCINE COMPONENTS WHEN SUBMITTED TO THE STUDENT'S SCHOOL: ~~Laboratory confirmation of positive titers are an acceptable alternative to the following vaccines when submitted to the student's school: DTaP, Hepatitis B, Varicella and MMR. For DTaP substitution, both the diphtheria and tetanus titers must be positive. For MMR substitution, titers for measles, mumps, and rubella must be positive. A titer is not an acceptable replacement for Haemophilus Influenzae type b, Pneumococcal, IPV, or Tdap vaccines.~~

1. FOR DTAP AND TDAP, BOTH THE DIPHTHERIA AND TETANUS TITERS MUST BE POSITIVE. A TITER IS NEVER ACCEPTABLE TO DEMONSTRATE IMMUNITY TO PERTUSSIS. THE DEPARTMENT WILL ACCEPT POSITIVE TITERS FOR TETANUS AND DIPHTHERIA. FOR PERTUSSIS THE DEPARTMENT WILL REQUIRE: 1) VACCINATION WITH AN AGE-APPROPRIATE PERTUSSIS-CONTAINING VACCINE SERIES IN ALIGNMENT WITH ACIP, OR 2) A CERTIFICATE OF MEDICAL OR NONMEDICAL EXEMPTION FOR THE PERTUSSIS COMPONENT.

2. FOR MMR, TITERS FOR MEASLES, MUMPS, AND RUBELLA MUST ALL BE POSITIVE. IF ANY SINGLE TITER IS NEGATIVE, THE DEPARTMENT WILL REQUIRE: 1) VACCINATION WITH AN AGE-APPROPRIATE MMR VACCINE SERIES IN ALIGNMENT WITH ACIP, OR 2) A CERTIFICATE OF MEDICAL OR NONMEDICAL EXEMPTION FOR THE COMPONENT(S) FOR WHICH THE TITER IS NEGATIVE.

3. FOR VARICELLA, THE TITER FOR VARICELLA MUST BE POSITIVE. IF THE TITER IS NEGATIVE, THE DEPARTMENT WILL REQUIRE: 1) VACCINATION WITH AN AGE-APPROPRIATE VARICELLA VACCINE SERIES IN ALIGNMENT WITH ACIP, OR 2) A CERTIFICATE OF MEDICAL OR NONMEDICAL EXEMPTION FOR THE VARICELLA VACCINE.

4. A TITER IS NOT AN ACCEPTABLE ALTERNATIVE FOR *HAEMOPHILUS INFLUENZAE* TYPE B, HEPATITIS B, THE PERTUSSIS COMPONENT OF TDAP AND DTAP VACCINES, PNEUMOCOCCAL, OR POLIO VACCINES.

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V. Denial of attendance

A. A student who is not in-process, not appropriately vaccinated for THEIR ~~his/her~~ age, or not exempt shall be denied attendance in accordance with the law.

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IX. Requirements for college and university students, colleges, and universities

The provisions below apply only to colleges or universities, or students enrolled in a college or university.

A. Minimum immunization requirements

1. Two valid doses of the MMR vaccine are required for all college or university students, unless the college or university student was born before 1957.

a. LABORATORY CONFIRMATION OF POSITIVE TITERS ARE AN ACCEPTABLE ALTERNATIVE TO THE MEASLES, MUMPS, AND RUBELLA VACCINE WHEN SUBMITTED TO THE STUDENT'S SCHOOL. TITERS FOR MEASLES, MUMPS, AND RUBELLA MUST ALL BE POSITIVE. IF ANY SINGLE TITER IS NEGATIVE, THE DEPARTMENT WILL REQUIRE: 1) VACCINATION WITH AN AGE-APPROPRIATE MMR VACCINE SERIES IN ALIGNMENT WITH ACIP, OR 2) A CERTIFICATE OF MEDICAL OR NONMEDICAL EXEMPTION FOR THE COMPONENT(S) FOR WHICH THE TITER IS NEGATIVE.

~~Laboratory confirmation of positive titers is an acceptable alternative to the MMR vaccine when submitted to the student's school. For MMR substitution, titers for each disease (measles, mumps, and rubella) must be positive~~

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B. Exemptions from immunization

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2. Nonmedical exemption - A student obtains a nonmedical exemption through the submission of the Department's Certificate of nonmedical exemption signed by the college or university student 18 years of age or older, emancipated college or university student, or the parent or legal guardian if the college or university student is under 18 years of age. Beginning with college or university entry, the Department's Certificate of nonmedical exemption must be submitted at enrollment. A Certificate of nonmedical exemption must also include either:

a. The signature of a person who is authorized pursuant to Title 12 to administer immunizations within THEIR ~~his or her~~ scope of practice, or

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